

undertaken to rationalize prescribing in an emergency department (ED).

METHODS: The annual census of our ED is 50,000 patients, 40% of whom receive prescription drugs. Prescriptions written by a total of 57 physicians were collected during 5 days before (P1) a 45-day intervention, then 5 days immediately after (P2) and 12 days, 3 years later (P3). The intervention was an educational program with emphasis on contraindications and adverse effects. Conforming indications were either established (E) (mainly rheumatological) or admitted (A) but controversial (trauma, ENT). For the latter, NSAIDs may be withheld. Between P1 and P2 all E&A indications were shown. Between P2 and P3, only the E indications were available. Prescribing errors were the main endpoint.

RESULTS: NSAIDs were prescribed for 37/434 patients (8.5%), 42/414 (10%), and 12/583 (2%), respectively ($p < 0.0001$). Between P1 and P2, prescribing errors decreased from 19% to 14% ($p = 0.76$). In P3, 1 was found. Between P1 and P3, conforming prescriptions increased from 81% to 92% ($p = 0.66$); NSAIDs decreased for trauma (50% to 8%; $p = 0.02$) and increased for rheumatology (19% to 42%; $p = 0.14$). Duration of treatment decreased from 8.0–4.0 days to 6.0–3.0 days ($p = 0.07$).

CONCLUSIONS: Overall NSAIDs as well as incorrect prescribing decreased after an intervention. However, 1) “Soft indications” stimulated prescribing; 2) Its curbing was obtained by a limited list between P2 and P3. This approach may be applied to other controversial drugs.

PAD2

OPTIMIZATION OF AN HMO'S NSAID PORTFOLIO FOLLOWING THE INTRODUCTION OF CELECOXIB

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Significant opportunities for patient safety are potentially achievable with the introduction of the cyclooxygenase-2 (COX-2) inhibitors. Unfortunately, constrained healthcare budgets may limit their use.

OBJECTIVE: To describe a NSAID therapeutic portfolio that maximizes medical benefits, but does not increase existing healthcare costs.

METHODS: A meta-heuristic assisted optimization of a typical HMO's NSAID portfolio after the introduction of celecoxib 200 mg QD was conducted using linear programming techniques. Current NSAID \pm antiulcerant usage and the cost of managing NSAID related gastropathy was derived from a large HMO. Background antiulcerant usage was established from an equivalent non-NSAID exposed arthritis population. The probabilities of NSAID related gastrointestinal events were derived from clinical trials and the literature. Decreased hospitalized gastrointestinal events without increasing the overall health budget were defined as the optimization criteria. Antiul-

cerant usage was not allowed to decrease below the background rate.

RESULTS: Assuming an average risk of NSAID-induced GI toxicity and 150 days/year of therapy, the average cost/patient/year for NSAID therapy and related adverse events would be \$366. If celecoxib is introduced into the healthcare system, 74% of patients could be switched to the agent without increasing the overall budget, provided that the remaining patients were distributed as follows: 13% generic ibuprofen; 9% generic NSAID + H2 blockers or prostaglandins; and 4% generic NSAID + PPI. During a 1-year period, this distribution of agents would result in 29 fewer physician visits and two less hospitalization per 1000 patients.

CONCLUSIONS: These results indicate that by optimizing the distribution of NSAIDs utilized within a HMO, a significant number of osteoarthritic patients can receive safer COX-2 specific compounds such as celecoxib without increasing the total budget.

PAD3

RESPONSIVENESS OF WOMAC IMPROVEMENT TO PATIENTS' AND PHYSICIANS' GLOBAL ASSESSMENT (PtGA & PhGA) OF IMPROVEMENT AMONG OSTEOARTHRITIS PATIENTS (OA)

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OBJECTIVE: To provide a clinically meaningful interpretation of improvements in WOMAC scores among OA patients.

METHODS: Data were obtained from three 12-week randomized clinical trials among 3369 OA flare patients. The Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC), PtGA & PhGA were administered at baseline and week 12. WOMAC is a 24-item instrument that contains three domains: pain, stiffness, and physical functioning and a summary score. PtGA & PhGA were measured on the following 5-point scale: very good, good, fair, poor, or very poor. Change scores were computed by subtracting patient's baseline from week 12 follow-up scores. Responsiveness was estimated as the mean change score corresponding to each level of PtGA or PhGA improvement.

RESULTS: At week 12, the number of patients experiencing improvements in PtGA and PhGA were: 1108 and 1158 for one-level, 708 and 745 for two-levels, and 368 and 311 for three or more levels. The average improvement of WOMAC domain and total scores among patients experiencing one, two, or three or more levels of PtGA improvement were 2.3, 4.4, 6.5 for pain, 1.0, 1.7, 2.5 for stiffness, 7.3, 13.9, 20.4 for physical functioning, and 10.1, 18.7, 27.4 for total WOMAC score. A similar responsiveness was found between average WOMAC scores and PhGA improvement, which were 2.3, 4.4, 6.6 for pain, 1.0, 1.7, 2.5 for stiffness, 7.5, 13.6, 21.0 for physical-functioning, and 10.3, 18.6, 27.9 for total WOMAC score.

CONCLUSION: Using change scores responding to a one-level improvement of PtGA or PhGA or using the average difference of change between any two levels improvement of PtGA or PhGA, the clinically meaningful improvement for WOMAC pain, stiffness, physical functioning, and total WOMAC scores were approximately 2, 1, 7, and 10, respectively.

PAD4

CLINICALLY MEANINGFUL IMPROVEMENT OF HEALTH-RELATED QUALITY OF LIFE (HRQoL) AMONG OSTEOARTHRITIS (OA) PATIENTS

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HRQoL measures are becoming important for evaluating the effects of arthritis treatments. Interpreting changes in HRQoL scores, however, has not been fully evaluated.

OBJECTIVE: To determine the clinically meaningful improvement of HRQoL as measured by the SF-36 among OA patients.

METHODS: Data were obtained from three 12-week randomized clinical trials among 3369 OA flare patients. The SF-36 and Patient Global Assessment (PtGA) were administered to patients at baseline and week 12. PtGA was measured on the following 1- to 5-point scale: very good, good, fair, poor, or very poor. Change scores were computed by subtracting patient's baseline from week 12 follow-up scores. Clinically meaningful improvement was estimated as the mean change score corresponding to a one-level improvement in PtGA. A similar interpretation of clinically meaningful changes was also performed using physician-global assessment, pain, and functional-status.

RESULTS: At week 12, the following patients experienced improvements in their PtGA rating: one-level (1158), two-levels (745), three or more levels (311), which corresponded to standardized physical and mental component scores (PCS & MCS) improvements of: one-level (3.8 and 1.4), two-levels (8.3 and 2.7), and three or more levels (10.4 and 4.2), respectively. The clinically meaningful improvement based on PtGA among OA patients were approximately 3.8 and 1.4 for PCS and MCS, respectively. The clinically meaningful changes for eight SF-36 domains were 7.2 for physical function, 13.1 for role physical, 11.6 for bodily pain, 2.1 for general health, 5.6 for vitality, 6.2 for social function, 7.7 for role emotion, 2.7 for mental health.

CONCLUSION: Clinically meaningful improvement varies between SF-36 domains and summary scores among OA patients. These results provide guidance in interpreting HRQoL results and planning clinical trials.

PAD5

RETROSPECTIVE EVALUATION OF CONCOMITANT GASTROINTESTINAL DRUG USE WITH NSAID THERAPY AMONG PATIENTS WITH ARTHRITIS

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Given the widespread use of NSAIDs and its association with gastric injury, the patterns and costs of gastric toxicity are of interest.

OBJECTIVE: The goal of this study was to describe the prevalence of concomitant antiulcer medication with NSAIDs.

METHODS: We identified patients diagnosed with osteoarthritis (OA) (ICD-9 codes: 715, 721.0, 721.3, 721.9), rheumatoid arthritis (RA) (ICD-9 codes: 714.0, 714.1, 714.2, 714.9) or both (OA/RA) between 1992 and 1997 using a managed care claims database. Study participants had at least 12 months of continuous health coverage (including drug benefits). We examined initial NSAID choice and the prevalence of concomitant gastrointestinal (GI) drug use (H2 antagonists [H2], proton pump inhibitors [PPI], prostaglandins [PS]) during the study period.

RESULTS: Among NSAID users (n = 40,350), ibuprofen (28.6%) and naproxen (18.2%) were most likely to be prescribed initially. Antiulcer medication use was more prevalent in patients receiving NSAID therapy, appeared to increase with age and vary by diagnosis: rates varied from 19.1% (OA), 19.6% (RA), 34.3% (OA/RA) in patients aged 18–39 to 29.2%, 32.3%, and 40.0% in patients aged 70–79. Fifteen percent of patients had a concomitant GI prescription added to their therapy within 60 days after the first NSAID prescription. Most of the anti-ulcerant use was H2 (76.9%), although PPI use (10.7%) and PS use (12.4%) increased in latter years.

CONCLUSIONS: We found that the prevalence of GI therapy varied by age and diagnosis and that concomitant GI medication use began soon after the initiation of NSAID therapy.

PAD6

ASSESSMENT OF THE ECONOMIC AND HUMANISTIC OUTCOMES OF THE WEST VIRGINIA MEDICAID'S PRIOR AUTHORIZATION POLICY FOR NSAIDS

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The West Virginia Medicaid's (WVM) prior authorization (PA) policy for NSAIDs is expected to produce savings to the WVM for two reasons: 1) NSAIDs are among the most frequently utilized drugs in WVM, and 2) while prices for NSAIDs vary substantially, most of the prescribed NSAIDs are the expensive ones. However, a concern arises whether the anticipated savings of policy implementation may be offset by increased costs of substitutable drugs and/or medical services. It is also im-